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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,676	06/06/2005	Shuji Hinuma	10577.0003-00000	8346

22852 7590 07/09/2007

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EXAMINER	
STOICA, ELLY GERALD	
ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
07/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/537,676	HINUMA ET AL.	
	Examiner	Art Unit	
	Elly-Gerald Stoica	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *1-7 and 10-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/06/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group IV (Claims 8-13) and of the specie EDG-2 receptor (seq. Id. No.: 1) in the reply filed on 06/07/2007 is acknowledged. The traversal is on the grounds that there exists a single general inventive concept that advances the art in that the EDG receptors are found in the kidney. This is not found persuasive because of the reasons of record. Moreover, the expression of EDG receptors in kidney sells was also known, as evidenced by Heringdorf et al. (Eur. J. Pharm., 414,145-154, 2001).

Status of the claims

2. Claims 1-21 are pending. Claims 1-7 and 14-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Claims 10-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction/election requirement in the reply filed on 06/07/2007.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8 and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to:

1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The claims are drawn to a method of screening for a preventive/therapeutic drug for diabetic nephropathy, chronic renal failure, nephritis, glomerulonephritis, interstitial renal disease or renal edema, which comprises using (i) lysophosphatidic acid or a salt thereof and (ii) an EDG-2 receptor comprising the same or substantially the same amino acid sequence as the amino acid sequence represented by SEQ ID NO: 1, its partial peptide, or a salt thereof, to screen a compound or a salt thereof that changes the binding property of lysophosphatidic acid or a salt thereof to said EDG-2 receptor or a salt thereof. Also claimed is a kit to be used according to the method claimed.

The state of the prior art was aware of the existence of methods of screening of EDG-2 modulators (U.S. Pat. Nos.: 6,485,922; 6, 252,056; 6, 875,757; Heise et al., Mol. Pharm., 60, 1173-1180, 2001; Sardar et al., Biochem. Biophys. Acta, 15682, 309-317, 2002). However, the correlation between the presence of the receptor in the kidney, and the diseases mentioned in the claim was not known and to this date is not known if there is any. In order for the potential modulator to be used as claimed there has to exist a level of knowledge as to the role played by the EDG-2 receptor in kidney diseases. There is no guidance from the Applicant in this respect and the only example provided merely states that EDG-2 receptor was found in the kidney of diabetic Wistar rats. Since no indication is presented with regard to the type of cells that have a higher expression of EGG-2 receptors, it may be that any of the cell types that constitute the tissue might have contributed to the result disclosed. There is no guidance or working example as to how a compound that modulates Lysophosphatidic Acid (LPA) binding to EDG-2 receptor would be used to treat, let alone prevent, the diseases claimed. Due to the unpredictability of the art with regard to the use of LPA/EDG-2 binding modulators, the lack of guidance and working examples from the inventor, the quantity of the experimentation necessitated to establish the feasibility of the modulator to be used in treatment of kidney diseases would be considered undue.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims contain the qualifier: "substantially the same" with regard to the amino acid Seq. Id.: 1. This term is indefinite because there is no quantitative limitation as to what its meaning is and therefore the meets and bounds of the claim could not be assessed. Also, with regard to Seq. Id No.: 1, the claim refers to "its partial peptide", which again is lacking any upper or lower limitation so that the meets and bounds of the claim could not be established.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 8 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Erickson et al. (U.S. Pat. 6, 485,922, 11/26/2002).

The claims are drawn to a method of screening for a preventive/therapeutic drug for diabetic nephropathy, chronic renal failure, nephritis, glomerulonephritis, interstitial renal disease or renal edema, which comprises using (i) lysophosphatidic acid or a salt thereof and (ii) an EDG-2 receptor comprising the same or substantially the same amino acid sequence as the amino acid sequence represented by SEQ ID NO: 1, its partial peptide, or a salt thereof, to screen a compound or a salt thereof that changes the binding property of lysophosphatidic acid or a salt thereof to said EDG-2 receptor or a salt thereof. Also claimed is a kit to be used according to the method claimed.

Erickson et al. teach a method for identifying compounds which modulate the activity of any of the EDG receptors, comprising the steps of exposing a compound and LPA to the EDG-2 receptor coupled to a response pathway, under conditions and for a time sufficient to allow interaction of LPA with the EDG-2 receptor and an associated response through the pathway, and b) detecting an increase or a decrease in the stimulation of the response pathway, relative to the absence of the tested compound (col. 6 from line 28 to col. 7, line 42). The Seq. Id. of the receptor mentioned by Erickson et al, Seq. Id No: 20, is identical to Seq. Id. No.: 1 of the instant application. Since the detection of any activation of the EDG-2 receptor is necessarily linked to the binding of the LPA to the EDG-2 receptor, the limitations of the claim8 and 9 is present in Erickson et al. Moreover, the intended use of the binding altering drug thus uncovered is not a precondition of the method so that the claims of the instant Application are anticipated by Ericksomn et al.

7. Claims 8 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Miller et al. (U.S. Pat. 6,875,757 04/05/2005).

Miller et al. teach method of modulating LPA activity on an LPA receptor which includes providing a compound of the present invention which has activity as an LPA receptor antagonist and contacting an LPA receptor with the compound under conditions effective to inhibit LPA-induced activity of the LPA receptor (col. 8, lines 10-40). One of the LPA receptors is EDG-2 (fig. 1). Again, any LPA activity through EDG-2 is in the wake of LPA binding to the EDG-2 receptor and thus the limitation existent in the claims of the instant Application is met. The considerations versus the intended use of the modulator were iterated supra. Therefore Miller et al anticipated the claims 8 and 9 of the application.

Conclusion

8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elly-Gerald Stoica whose telephone number is (571) 272-9941. The examiner can normally be reached on 8:30-17:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER